

On file
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skin a synergistic composition which does not contain a corticosteroid [comprising] consisting essentially of ~~effective amounts of~~ 4-hydroxyanisole and [a] at least one retinoid selected from the group consisting of all-trans retinoic acid, (N-acetyl-4-aminophenyl) retinoate and 11-cis, 13-cis-12-hydroxymethyl retinoic acid δ -lactone in a pharmaceutically acceptable topical vehicle.--

Remarks

Favorable reconsideration, in view of the above amendments and these remarks, is respectfully requested.

The amendment to claims 1 and 11 inserts Markush groups of the three retinoids recited in the 35 USC 112 rejection set out in paragraph 15 of Paper No. 5. Accordingly, that rejection is believed to be rendered moot.

Claims 1, 2, 5, 8, 11, 12, 15 and 18 are rejected under 35 USC 112, first paragraph, as enabling only for claims limited to compositions containing specific amounts of 4-hydroxyanisole and retinoids. Applicants traverse.

Applicants have discovered that 4-hydroxyanisole and certain retinoids, when used in combination, are synergistic where skin depigmentation is concerned. They do not intend to claim all amounts of these ingredients, but, rather, all amounts which give the synergistic effect. Given applicants' basic concept, it requires only reasonable experimentation by a skilled routineer to determine suitable amounts which produce the claimed effect. Reconsideration is requested.

Claims 1, 2 and 3 were rejected under 35 USC 102(b) as anticipated by Marks or Papa. Both Marks and Papa show butylated hydroxyanisole in topical compositions along with all-trans-retinoic acid and zinc salts of that acid, respectively. Applicants traverse.

Applicants agree that the Marks and Papa references teach

butylated hydroxyanisole and either tretinoin or a tretinoinsalt. It is unclear to applicants how these teachings can be deemed to anticipate the instant claims (under 35 USC 102).

Butylated hydroxyanisole--which Marks and Papa recite--and 4-hydroxyanisole--which applicants claims--are distinct chemical compounds having totally different functions. Thus, the cited references cannot anticipate claims 1, 2 and 3 because these claims require the use of a compound--i.e., 4-hydroxyanisole--which the references do not mention.

Withdrawal of this ground of rejection is solicited.

Claims 1-20 were rejected under 35 USC 103 as unpatentable over Kligman (Canadian 982,945) in view of Kligman (U.S. 3,856,934). Applicants traverse.

The Canadian Kligman patent recites--as does the U.S. Kligman patent--a three component composition for depigmenting skin. The patented compositions include a hydroquinone-type bleaching agent, a retinoic acid irritant/exfoliant and an anti-inflammatory corticosteroid. The steroid component is always present.

The U.S. patent to Kligman also teaches that a steroid must be present in a three component formulation. At column 3, lines 15-22, patentee states that "hydroquinone and retinoic acid was ineffective to provide complete depigmentation" (column 3, lines 18 and 19). The same ineffectiveness was noted for the combination of dexamethasone and hydroquinone (column 3, lines 15-18).

It is clear, then, that both Kligman patents teach away from two component combinations of a hydroxyquinone-type bleach and a retinoid--i.e., the very combinations which applicants claim.

Note, too, that claims 1 and 11 now recite "consisting essentially of" in their preambles. As the Office knows, this phrase excludes the use of ingredients--such as Kligman's steroid--which would significantly affect the function of

applicants' 4-hydroxy anisole/retinoid combinations. (Obviously, Kligman's teaching that the steroid is needed implies that--at least in his mind--the steroid would affect the function of the other two ingredients.)

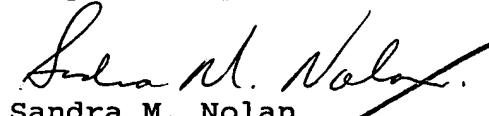
Reconsideration and withdrawal of this ground of rejection are requested.

In sum:

- (a) Marks and Papa do not show 4-hydroxyanisole, so they cannot anticipate applicants' claims; and
- (b) Kligman and Kligman teach away from compositions which exclude steroids.

Since none of the references, taken alone or in combination, can be fairly said to suggest the invention, allowance of claims 1-20 is respectfully requested.

Respectfully submitted,


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